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W81XWH-16-2-0061

TITLE:
MORE Resiliency in the Rehabilitation of Active Duty Service Members

PRINCIPAL INVESTIGATOR:
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CONTRACTING ORGANIZATION:
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14. ABSTRACT The purpose of our proposed multicenter prospective cohort study is to address important knowledge gaps on resiliency in the rehabilitation of adults with lower-extremity injuries. Specific aims are to develop and test a resiliency instrument that is relevant to active duty military Service Members. The proposed project will leverage the infrastructure of the Maximizing Outpatient Rehabilitation Effectiveness (MORE) study that is currently being conducted at Brooke Army Medical Center. The first year of the project will focus on selecting items from three well-established resiliency instruments that have been validated in civilian populations. Interviews and focus groups will be conducted in 44 active duty military Service Members. A pre-test in 50 Service Members will finalize the instrument. Testing in 310 Service Members will occur in the second and third year of the project to determine the reliability and construct and predictive validity of the MORE resiliency instrument in active duty Service Members with lower-extremity injury. To date, this project is pending HRPO approval and no research procedures have been conducted.					
15. SUBJECT TERMS Resiliency, lower-extremity injury, instrument development					
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TABLE OF CONTENTS

	<u>Page No.</u>
1. Introduction	4
2. Keywords	4
3. Accomplishments	4
4. Impact	5
5. Changes/Problems	6
6. Products	6
7. Participants & Other Collaborating Organizations	7
8. Special Reporting Requirements	8
9. Quad Chart	9

1. INTRODUCTION:

The overall objective of this multicenter prospective study is to develop and validate a standardized measure to objectively assess resiliency following neuromusculoskeletal injury. The measure will be specifically tailored to the injured Service Member. Results from the proposed study will provide an evidence-based resiliency instrument that can be integrated into rehabilitation care in the military setting with the end goal of improving rehabilitation outcomes.

This study has 4 specific aims: 1) To select items for a resiliency instrument that address multiple dimensions of resiliency for active duty military Service Members 2) To perform a pre-test of the resiliency instrument in active duty military Service Members with lower-extremity injury for item reduction 3) To determine the reliability and construct validity of a resiliency instrument in active duty military Service Members with lower-extremity injury 4) To determine the predictive validity of a resiliency instrument in active duty military Service Members with lower-extremity injury.

This project will leverage the infrastructure of the Maximizing Outpatient Rehabilitation Effectiveness (MORE) study that is currently being funded by the Bridging Advanced Developments for Exceptional Rehabilitation Consortium (W81XWH-11-2-0222). We propose a three-phase design. In Phase 1, we will identify the most relevant resiliency items to active duty Service Members by conducting interviews and focus groups with individuals who are currently enrolled in the MORE study (N=44). In Phase 2, pre-testing will be conducted to refine and eliminate items that perform poorly (N=50). In Phase 3, we will conduct a prospective cohort study to determine reliability and construct and predictive validity (N=310). We plan to recruit a total of 404 MORE participants from the Center for the Intrepid and CPT Jennifer M. Moreno Primary Care Clinic at Brooke Army Medical Center.

2. KEYWORDS:

resiliency, instrument development, reliability, validity, lower-extremity trauma, rehabilitation outcomes

3. ACCOMPLISHMENTS:

What were the major goals of the project?

	Timeline (Months)	% Complete
Major Task 1: Regulatory Approval		
Milestone(s) Achieved		
Local IRB Approval	3	100%
USAMRMC HRPO Approval	4	0%
Personnel Hired	4	100%
Major Task 2: Participant Interviews		
Milestone(s) Achieved:		
20 Interviews Completed	7	0%
Qualitative Model and Narratives Completed	8	0%
Major Task 3: Participant Focus Groups		
Milestone(s) Achieved:		
3 Focus Groups Completed	11	0%

Initial Resiliency Instrument Completed	12	0%
Major Task 4: Pre-Test of Instrument		
Milestone(s) Achieved:		
50 Participants Complete the Pre-test	15	0%
Resiliency Instrument Finalized	16	0%
Major Task 5: Test-Retest Reliability		
Milestone(s) Achieved:		
Test-Retest Reliability Completed	20	0%
Major Task 6: Construct Validity		
Milestone(s) Achieved:		
Construct Validity Completed	28	0%
Major Task 7: Predictive Validity		
Milestone(s) Achieved:		
Predictive Validity Completed	36	0%
Final Report Completed	36	0%

What was accomplished under these goals?

For this reporting period, major activities included hiring personnel and IRB approval as well as revising the SOW and budget to accommodate a site PI change at Brooke Army Medical Center (BAMC). The study protocol was approved by Vanderbilt IRB on September 6, 2016 and by BAMC IRB on October 12, 2017. IRB letters have also been obtained from University of Iowa and Johns Hopkins Medicine for collaboration with Drs. Wilken and Wegener and these IRB letters confirm a not human subjects research determination. All IRB approved documents were submitted for HRPO review on October 19, 2017.

What opportunities for training and professional development has the project provided?

Nothing to Report

How were the results disseminated to communities of interest?

Nothing to Report

What do you plan to do during the next reporting period to accomplish the goals?

During the next reporting period, we plan on obtaining HRPO approval and conducting participant interviews and focus groups as outlined under Major Task 2 and 3.

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

Nothing to Report

What was the impact on other disciplines?

Nothing to Report

What was the impact on technology transfer?

Nothing to Report

What was the impact on society beyond science and technology?

Nothing to Report

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

The major change for this project was the change in site PI for the BAMC site. Dr. Wilken left BAMC and started a position at the University of Iowa. Amy Bowles MD, Deputy Chief in Department of Rehabilitation Medicine at BAMC, became the designated site PI for this project. This led to a revised SOW and budget and a delay in IRB submission at BAMC. There has been no change to the research approach.

Actual or anticipated problems or delays and actions or plans to resolve them

The change in site PI at BAMC has delayed this project. However, this has now been resolved. A revised SOW and budget have been approved and the project has received IRB approval from all sites including BAMC. Once HRPO approval is received, we anticipate completing milestones for major task 2 and 3 in the next reporting period.

Changes that had a significant impact on expenditures

Due to the delay in IRB approval and the need for a revised budget, the personnel and research related expenditures have been lower than expected for the reporting period.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to Report

Significant changes in use or care of human subjects

Nothing to Report

Significant changes in use or care of vertebrate animals.

Not Applicable

Significant changes in use of biohazards and/or select agents

Not Applicable

6. PRODUCTS: List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."

- **Publications, conference papers, and presentations**

Nothing to Report

Journal publications. Nothing to Report

Books or other non-periodical, one-time publications. Nothing to Report

Other publications, conference papers, and presentations. Nothing to Report

- **Website(s) or other Internet site(s)**

Nothing to report

- **Technologies or techniques**
Nothing to report
- **Inventions, patent applications, and/or licenses**
Nothing to report
- **Other Products**
Nothing to report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name: Kristin Archer

Project Role: PI

Nearest person month worked: 1

Contribution to project: Developed protocol and all IRB documents, HRPO submission, completed quarterly reports and annual report

Name: Amy Bowles

Project Role: Site PI BAMC

Nearest person month worked: 1

Contribution to project: Oversight of BAMC IRB submission

Name: Chrissy Haug

Project Role: Project Director

Nearest person month worked: 1

Contribution to project: Oversight of VUMC IRB submission, assisted with BAMC IRB submission

Name: Cynthia Chaiyanam

Project Role: Research Assistant

Nearest person month worked: 1

Contribution to project: Prepared BAMC IRB documents and submitted documents to BAMC IRB

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to report

What other organizations were involved as partners?

Organization Name: University of Iowa

Location of Organization: Iowa City, IA

Partner's contribution to the project:

Collaboration on protocol and IRB documents

Organization Name: Johns Hopkins Medicine

Location of Organization: Baltimore, MD

Partner's contribution to the project:

Collaboration on protocol and IRB documents

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: N/A

QUAD CHARTS: Submitted

MORE Resiliency in the Rehabilitation of Active Duty Service Members

OR150140

W81XWH-16-2-0061



PI: Kristin R. Archer

Org: Vanderbilt University Medical Center

Award Amount: \$499,999

Study/Product Aim(s)

- Aim #1: To select items for a resiliency instrument that address multiple dimensions of resiliency for active duty Service Members.
- Aim #2: To perform a pre-test of the resiliency instrument in active duty Service Members participating in the MORE study.
- Aims #3/4: To determine the reliability and validity of the resiliency instrument in Service Members participating in the MORE study.

Approach

Conduct a prospective observational study in 310 active duty Service Members who have experienced lower limb injury and are participating in the MORE study at Brooke Army Medical Center. Psychometric statistics and multivariable linear regression will establish reliability and construct and predictive validity.



An improved understanding of resiliency and its relative contribution to rehabilitation success and physical function and performance is needed to effectively guide the use of limited clinic resources and facilitate efforts to maximize outpatient rehabilitation effectiveness.

Timeline and Cost

Activities	CY	16	17	18	19
Regulatory Approval					
Item Selection					
Item Reduction (Pre-Test)					
Reliability and Validity Testing					
Estimated Budget (\$K)		\$8	\$21	\$235	\$235

Updated: October 20, 2017

Goals/Milestones

CY16-17 Goal – Regulatory approval

- ☒ BAMC IRB approval obtained
- ☐ Interviews and focus groups conducted

CY18 Goal – Enrollment and data collection

- ☐ Initial resiliency instrument developed
- ☐ Enroll 50 participants and complete pre-test of instrument
- ☐ Start enrollment for validity testing cohort

CY19 Goal – Follow-up, data analysis

- ☐ Collect complete follow-up data on 85% of cohort participants
- ☐ Complete reliability and validity analyses
- ☐ Presentation of results to clinical staff and national meetings
- ☐ Manuscript and final report submission

Comments/Challenges/Issues/Concerns: Delay in BAMC IRB/HRPO submission due to change in BAMC site PI

Budget Expenditure to Date

Projected Expenditure: \$ 499,999

Actual Expenditure: \$11,392